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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,815	06/08/2001	Takashi Ito	46342/55965	9695

21874 7590 02/24/2004

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/857,815

Applicant(s)

ITO ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,13,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 17 is/are rejected.
- 7) ☒ Claim(s) 12,13 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/15/04</u> . | 6) <input type="checkbox"/> Other: _____  |

***Status of Application, Amendments and/or Claims***

The amendment filed 18 November 2003 has been entered in full. Claims 3-11, 14 and 16 were cancelled. Claim 17 was added. Claims 1, 2, 12, 13, 15 and 17 are pending.

The information disclosure statement filed 15 December 2003 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The specification is now in compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The objection of claims 2, 5-7, 10 and 11 as set forth at page 3 of the previous Office Action (22 May 2003) is *withdrawn* in view of the amendment (18 November 2003).

The rejection of claims 1, 2, 12, 13, 15 and 17 under 35 U.S.C. 112, first paragraph, enablement as set forth at pages 3-6 of the previous Office Action (22 May 2003) is *withdrawn* in view of the amendment (18 November 2003).

The rejection of claims 3-11 under 35 U.S.C. 112, second paragraph as set forth at page 6 of the previous Office Action (22 May 2003) is *withdrawn* in view of the amendment (18 November 2003).

**Claim Rejections - 35 USC § 102(e)**

Claims 1, 2 and 17 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wei *et al.*, US Patent No. 6,410,506 B1. The basis for this rejection is set forth at pages 6-7 of the previous Office Action (22 May 2003).

Applicants state that as amended, claim 1 is directed to a betacellulin mutein or a salt thereof comprising the amino acid sequence represented by SEQ ID NO: 38, wherein the pancreatic beta cell differentiation promoting activity is preserved, and the epithelial cell growth promoting activity is reduced. Applicants maintain that the sequence disclosed by Wei *et al.* is a 177 amino acid polypeptide and Wei *et al.* does not specifically disclose the isolated 53 amino acid peptide of SEQ ID NO:38, or specify the desirability of using a peptide comprising this specific sequence. Furthermore, Wei *et al.* does not disclose a polypeptide of SEQ ID NO:38, wherein the pancreatic beta cell differentiation promoting activity is preserved, and the epithelial cell growth promoting activity is reduced.

Applicants' arguments have been fully considered but not deemed persuasive because claim 1 recites "comprising the amino acid sequence represented by SEQ ID NO:38". Thus the claims read on any sequence comprising SEQ ID NO:38 (open language). Wei *et al.* teach an amino acid sequence comprising the sequence represented by SEQ ID NO:38 (Wei *et al.*, SEQ ID NO:13, amino acids residues 55-123). Furthermore, a compound and all of its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

### **Claim Objections**

Claims 12, 13 and 15 are objected to for depending from a rejected claim.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:00 p.m.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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2/19/04



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